

检验报告单
Certification of Analysis

品名	葡甲胺		
Product Name:	N-Methyl-D-Glucamine (Meglumine)		
批号	批数量		
Batch No.:	PJ1507548	Batch Quantity:	1000kg
生产日期	包装规格		
Manufacturing Date:	2015.07.30	Packing Size:	25kg/桶
复检期	报告日期		
Retest Date:	2017.07.29	Report Date:	2015.07.30
标准依据	USP27 版标准 (the standard of USP 27th Edition)		
Quality Standard:			

项目 Test Items	标准 Specifications	检验结果 Results
外观 Appearance	白色结晶性粉末 White crystalline powder	白色结晶性粉末 White crystalline powder
熔点 Melting point	128-132°C	128.3-130.0°C
灼烧残渣 Residue on ignition	≤0.1%	0.04%
干燥失重 Loss on drying	≤0.5%	0.26%
含量 Content	≥99.0%	99.47%
比旋度 Specific optical rotation	-15.5°—-17.5°	-16.14°
重金属 Heavy metals	≤10ppm	符合规定 Accords With the Specification
还原物 Absence of reducing substance	蓝色不变为红色 Blue don't change to red	符合规定 Accords With the Specification
溶液澄清晰度 Clarity of the solution	无色透明澄清液体 Clear and colourless solution	符合规定 Accords With the Specification
吸光度 Ultraviolet absorbancy degree	≤0.03	0.01
易炭化物 Readily carbonizable substance	不深于橙红色 2 号 No deeper than the orange red no. 2	符合规定 Accords With the Specification
镍盐 Nickel	≤5ppm	2ppm
结论 Conclusions:	符合 USP27 版标准 Meeting the standard of USP 27th Edition	
报告人 Prepared by:	复核人 Reviewed by:	批准人 Approved by:
 签名/日期 Name/Date	 签名/日期 Name/Date	 签名/日期 Name/Date

质量检验专用章